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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,754

08/11/2006

Richard A. Gibbs

P27-051US

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EXAMINER

KATAKAM, SUDHAKAR

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

09/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,754	Applicant(s) GIBBS ET AL.	
	Examiner Sudhakar Katakam	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-13, 15-24, 26-36 and 39-43 is/are pending in the application.
- 4a) Of the above claim(s) 4-8, 10, 11, 15, 18, 19, 21 and 26-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 3, 9, 12, 13, 16, 17, 20, 22-24, 35-36, 39, 40 and 43 is/are rejected.
- 7) ☒ Claim(s) 41 and 42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/11/05, 7/16/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Restriction

1. Applicant's response to restriction requirement and election of group I (claims 1-36 and 39) with traverse in the reply filed on 27th June 2008 is acknowledged. In addition, applicants further elected a single species (see in the applicant's response). The applicants traversal of the restriction is on the basis that the "complete search of all groups could be carried out without undue burden on the office". This is not found persuasive because the claims of groups I-III belongs to divergent structural compounds and diseases. Each of the above groups is belongs to a divergent subject matter, and there is no common technical feature to combine the groups, and hence the restriction is proper. Because these inventions are independent or distinct, there would be a serious burden on the examiner if restriction were not required; because the inventions require a different field of search (see MPEP § 808.02) restriction for examination purposes as indicated is proper.

Therefore, the inventions are independent or distinct because prior art anticipating and/or rendering obvious one group would not necessarily anticipate and/or render obvious the other group. Hence, there will be a serious burden on the examiner if restriction is not required because the inventions require a different field of search. Therefore, restriction for examination purposes as indicated is proper.

Applicants' elected compound reads the claims 2, 3, 9, 12, 13, 16, 17, 20, 22-24, 35-36 and 39-43.

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In view of the foregoing reasons, claims 4-8, 10-11, 15, 18-19, 21, 26-34 are withdrawn from further consideration as not being drawn to an elected invention and species.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 23-24 and 39 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for “treating cancer” as claimed.

With regard to rejection under 35 USC 112 first paragraph, the following factors have been carefully considered (In re Wands, 8 USPQ2d 1400; CAFC, 1988):

1. The nature of the invention,
2. The state of the prior art,
3. The predictability or lack thereof in the art,
4. The amount of direction or guidance present,
5. The presence or absence of working examples,
6. The breadth of the claims,
7. The quantity of experimentation needed, and
8. The level of the skill in the art.

(1). **Nature of the invention:** The claimed invention is drawn to a method of treating cancer with the compound of formula III recited in claim 40.

(2). **Breadth of the claims:** The claims are extremely broad. In particular claims read on treating any and all forms of cancer comprising administering to a patient a

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therapeutically effective amount of a compound of the formula recited in claim 40. The number of compounds encompassed by formula is vast. The claim 39 recites specific forms of cancer, i.e., cancer of stomach, colon, rectal, liver, lung etc.

(3). **State of the Prior Art:** The prior art (Gibbs et al, 1997, Annual Review of Pharmacology and Toxicology) teach an analogous compounds of the applicants' formula and contemplates their use as cancer chemotherapeutics. No cancers are effectively treated.

(4). **Unpredictability of the Art:** A method of "treating claimed cancers" is a subject with the applicants' compounds of present invention is speculative and unpredictable. The claims are drawn to treating various cancers, by administering a compound having formula as recited in the claim 40. However, there is no information provided regarding administering and treating the cancer and a predictable correlation between the various cancers and the claimed compounds. Thus a correlation between the ability to inhibit the tumor cell growth and predictable treatment of the claimed diseases is not established.

(5). **Amount of Guidance Provided:** Applicants have provided no guidance for using the claimed method to "treat the claimed cancer diseases" in a subject. The instant disclosure states that the compounds of formula inhibitors of isoprenylcysteine methyltransferase in the cells. There is no further information or guidance provided regarding how one of skill in the art would use this disclosure to effectively treat various cancers listed in the claims.

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(6). **Presence or Absence of Working Examples:** There are no examples of “treating cancers” in a subject disclosed.

(7). **Ordinary Skill in the Art:** The ordinary skill in the art is high.

(8). **Amount of Experimentation Necessary:** In light of the state of art, the unpredictability of the art and amount of guidance provided, as discussed above, the amount of experimentation necessary to practice the current methods is undue. While one may expect to be inhibitors of isoprenylcysteine methyltransferase in the cells to some extent, especially *in vitro*, one of ordinary skill in the art would have to perform experimentation to determine which compounds if any are effective *in vivo*. One of skill in the art would then have to determine which if any cancer diseases may be effectively treated by administration of the as yet unidentified active and effective compounds. One of skill in the art is provided with no guidance regarding selection of compound, dosage, duration, or route of administration. The amount of experimentation necessary to identify useful compound in a form useful to treat the claimed inventions is not routine.

Thus, it can safely be concluded that the instant disclosure fails to provide an enabling disclosure for the “treating cancer” with the applicants’ compound of formula.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 22 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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6. Claim 22 recites the phrase "effective amount", however the claim fails to state the function which is to be achieved and more than one effect can be implied from the specification or the relevant art. Claim 22 is therefore rendered indefinite.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 40, 43, 2-3, 9, 12-13, 16-17, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by **Stock** (US 5,043,268) or **Rando** (US 5,202,456).

Stock anticipates the instant claims, see below:

The present invention pertains to cysteine derivatives having the formula:



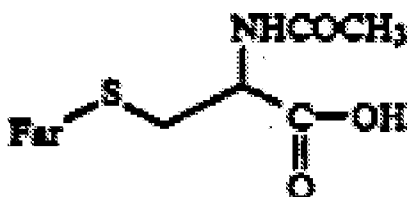
in which:

R¹ is alkyl of 1 to 3 carbon atoms;

R² is —COX; wherein X is —OH, —OCH₃, —NH₂, —NHR⁴, —N(R⁴)₂ or halogen;

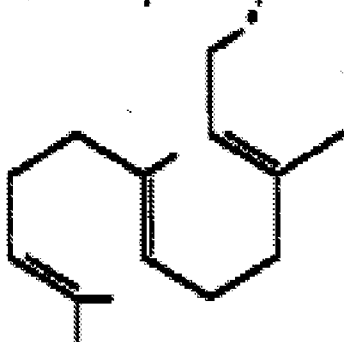
R³ is a straight or branched chain alkyl of 10 to 25 carbon atoms, a straight or branched chain alkenyl, including polyunsaturated alkenes, of 10 to 25 carbon atoms;

Rando also discloses the instant applicants' compound (col.13 and 14), see below:



, where Far is

For the compounds depicted in this table "Far" means a farnesyl group, i.e., the moiety:



, which

anticipates the instant claims.

9. Claims 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by **Ma et al** (Biochemistry, 1994, 33, 5414-5420).

Ma et al disclose the applicants' compound(s) which are inhibitors of isoprenylated protein methyltransferase [see discussion in page 5420].

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sudhakar Katakam/
Examiner, Art Unit 1621

/SHAILENDRA - KUMAR/
Primary Examiner, Art Unit 1621